

Creating a Patent Clearinghouse in Canada: A Solution to Problems of Equity and Access

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Two of the most pressing normative questions surrounding biotechnology patenting today relate to the equitable distribution of the products of biotechnological research and ensuring fair access to those products. Often discussed under the heading “benefit sharing”, the problem of the equitable distribution of biotechnology’s advances is a mixture of two normative concerns: whether there is a universal right to benefit from scientific progress and whether particular research subjects have a right to share in the benefits of research using their tissues. The question of access is similarly twofold. On one hand, researchers are concerned that patent rights may block second generation innovation by placing licensing and monetary roadblocks in the way of research. This is the so-called “anticommons” problems that has been discussed theoretically but has yet to be demonstrated or disproved empirically. The second aspect of this question is patient access to new technologies, such as new screening tests or potential treatments based on the use of stem-cells.

This poster focuses on a few legal mechanisms that may facilitate both access to biotechnology’s products and the equitable distribution of the benefits arising from those products. In particular, we suggest the creation of an independent and non-profit patent clearinghouse. This clearinghouse would administer patents in a particular field of study (e.g., all stem cell related patents) and would distribute income to patent holders arising from that administration. Specifically, the clearinghouse would charge a fixed fee for use of patent rights that would be distributed to patent owners. At the same time, the clearinghouse would

hold back a certain percentage of profits (the HUGO Ethics Committee recommends, for example, between 1 and 3%) for redistribution to health care infrastructure in low-income countries. The clearinghouse would ensure that all researchers have fair access to innovations in the field while ensuring a fair economic return to patentees.

What is a Patent?

A patent is a government grant of a time-limited legal monopoly given to an inventor in exchange for the public disclosure of an invention. It can be thought of as a veto over the activities of others in respect of making, using, selling or importing an invention.

It permits the inventor or an assignee (often a corporation) to commercially exploit the invention.

What are the Criteria for Patentability in Canada?

An invention, to be patentable, must be “new”, “useful” and “non-obvious”. These are legal terms that have been defined in Canadian case law as follows:

New – the invention must not have been previously disclosed in a single source more than 12 months prior to the filing of the patent application.

Useful – the invention must work and must be of industrial interest.

Non-obvious – To be patentable, an invention must be a development or an improvement that would not have been obvious beforehand to persons skilled in the art.

The Current International Trend

To mitigate the anticommens effect that patents have on access to novel biotechnological applications, mechanisms to promote “benefit-sharing” and to facilitate access to medicine have been suggested by the Human Genome Organization, The United Nations and the World Trade Organization.

Human Genome Organization Ethics Committee, Statement on Benefit Sharing

1. In the interest of justice, there is an evolving international consensus that suggests that groups participating in genetic research should receive some benefit.
2. Permissible benefit-sharing mechanisms may include: “*agreements with individuals, families, groups, communities or populations that foresee technology transfer, local training, joint ventures, provision of health care or of information infrastructures, reimbursement of costs, or the possible use of a percentage of any royalties for humanitarian purposes.*”
3. Benefit-sharing does not include “undue inducement” to individuals, families or populations.

See, HUGO Ethics Committee, *Statement on Benefit-Sharing*, April 9, 2000, online: HUGO <<http://www.gene.ucl.ac.uk/hugo/benefit.html>>.

United Nations Convention on Biological Diversity & the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization

1. provides an example of how international law has been shaped to require benefit sharing in the context of non-human genetic resources
2. provides framework that is potentially applicable to human genetic resources

See, United Nations, *Convention on Biological Diversity*, June 5, 1992, 31 I.L.M. 818, online: CBD <<http://www.biodiv.org/convention/articles.asp>>.

See also, *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization*, online: CBD <<http://www.biodiv.org/programmes/socio-eco/benefit/bonn.asp>>.

World Trade Organization (WTO) Declaration on the TRIPS Agreement & Public Health, November 14, 2001

1. This statement, though not directly applicable to the dissemination of genetic technologies in the developed world provides a timely example of how social concerns of member states has made its way to the forefront of international trade negotiations. Specifically, the DOHA declaration provides that:
 1. The TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.
 - b. The Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.

See, World Trade Organization, *Declaration on the TRIPS Agreement and Public Health*, Doc. WT/MIN(01)/Dec/2, online: WTO <http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm>.

The following legal mechanisms can be used to facilitate access and the equitable sharing of the benefits of patented technologies:

1. **Cross-licensing arrangements** – The exchange of IP rights between two or more persons. Cross licensing is effective between patent holders with the time and human resources to carry out negotiations.

Con – Cross-licensing is an ineffective mechanism for new entrants into the research market as they have nothing to trade. They are also ineffective for when licenses are required from a large number of patent holders because of the time and expense of negotiations.

2. **Patent pools** – The aggregation of IP rights that are the subject of cross licensing arrangements, whether transferred directly by the patentee to a licensee or through some medium, such as a joint venture set up specifically to administer the patent pool.

Con – To be effective, patent pools must relate to a clear technological platform. This is missing in biotechnology since there is no one ‘standard’ in the field.

3. **Independent and non-profit patent clearinghouse** – A “clearinghouse” is any agency that brings together seekers and providers of goods, services or



information, thus matching demand and supply. A patent clearinghouse would function in much the same way as a copyright collective – it would administer the rights of several patent owners; authority would be granted by the patent owner to the collective to set license terms to others who would be permitted to work the patent. The patent clearinghouse would be made available to all users of the technology and users would pay only for those patents they require. The fee would be standard and, given the lack of negotiation, the transaction costs would be low.

Con – The biggest problem with this suggestion is having industry agree to participate. It would probably require government pressure on industry to establish such a patent clearinghouse. There is precedent for this in the aero and radio industries in the US.

Conclusions

Of the options discussed above, the creation of an independent and non-profit patent clearinghouse appears to be the best option because:

1. It would ensure that all researchers have fair access to innovations in the field; and
2. It would also ensure a fair economic return to patent holders.

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Human Genes are Considered Patentable Subject Matter in Canada

It is typically assumed that patents are necessary

- As an incentive for technological innovation;
- For biotechnology firms to obtain investment capital; and
- To recoup research and development costs.

Increasingly, however, critics of the existing patent system suggest that biotech patents

- Decrease innovation
- Encourage academic secrecy;
- Decrease societal access to new technologies;
- Increase “medicalization” of normal human conditions; and
- Diminish public trust in science, technology and research.

The following examples illustrate how patents can negatively affect the equitable distribution of biotechnology’s advances and can undermine access to new medical technologies

Canavan Disease

- Canavan disease is a rare genetic disease that leads to degeneration of the brain and results in mental retardation, loss of motor skills and other symptoms; there is a higher incidence in those of Ashkenazi Jewish and French Canadian ancestries.
- Research to identify the disease gene was spearheaded and funded by families (and organizations established by families) affected by Canavan disease.
- Dr. Reuben Matalon and the Miami Children’s Hospital, received funding from the Canavan Foundation to identify the disease gene and to develop pre-natal and carrier screen tests for Canavan disease.
- Once tests were developed, testing was offered free of charge by the Canavan Foundation at Mt. Sinai Hospital in New York.
- A dispute has since arisen and the families have filed a law suit against Dr. Matalon and the Miami Children’s Hospital alleging that unbeknownst to the families and related organizations, Dr. Matalon and the Miami Children’s Hospital, secretly obtained a patent (United States Patent 5,679,635, “*Aspartocylase Gene, Protein and Methods of Screening Formulations Associated With Canavan Disease*”) for the Canavan disease gene they discovered using the genetic information and financial resources provided by the Canavan families and began to charge royalties and limit the availability of Canavan testing.
- The lawsuit alleges breach of informed consent, breach of fiduciary duty, unjust enrichment, fraudulent concealment, conversion, and misappropriation of trade secrets.
- In the lawsuit, the Canavan families and organizations seek injunctive relief to prevent Miami Children’s Hospital from restricting access to prenatal and carrier testing for Canavan disease and from impeding research on finding a cure or therapies for Canavan disease through enforcement of its patent.
- This law suit is important and may have far-reaching implications concerning the legal rights of research participants with respect to patents.

See, “Background Information on Greenberg v. Miami Children’s Hospital, *et al*”, online: Chicago-Kent College of Law <<http://www.kentlaw.edu/islt/canavanupdate.html>>.

See also, Canavan Foundation, online: <<http://www.canavanfoundation.org/news.php>>.

See also, United States Patent and Trademark Office, Patent Full-Text and Full-Page Image Databases, online: USPTO: <<http://www.uspto.gov/patft/index.html>>.

Myriad Genetics & Hereditary Breast Cancer

1. Myriad Genetics Inc., is a U.S. firm based in Salt Lake City Utah; it has successfully obtained U.S., European and Canadian patents on BRCA1 and BRCA2 genes, two genes associated with familial breast and ovarian cancer.
2. Canadian patents of particular interest include:
 - a. 2,196,797, "*In-Vivo Mutations and Polymorphisms in the 17-Q Linked Breast and Ovarian Cancer Susceptibility Gene*";
 - b. 2,196,795, "*Method for Diagnosing a Predisposition for Breast and Ovarian Cancer*";
 - c. 2,196,790, "*17Q-Linked Breast and Ovarian Cancer Susceptibility Gene*" and
 - d. 2,239,733, "*Chromosome 13-Linked Breast Cancer Susceptibility Gene*".
3. In the summer of 2001, Myriad took steps to enforce its patent rights as against publicly funded testing labs in Canada that perform BRCA1 and BRCA2 testing.
4. Myriad alleges that the Canadian labs are infringing its patents and has demanded that all testing must be done through Myriad's or labs affiliated with Myriad.
5. At \$3,850, Myriad's test costs the Canadian health care system two to three times more than tests routinely performed in Canada at publicly funded laboratories.
6. Canadian provinces have been inconsistent in their responses to Myriad's demands:
 - a. **Quebec** – samples are sent to Myriad for analysis; testing continues to be publicly funded.
 - b. **British Columbia** – has stopped all testing; will facilitate testing through Myriad for patients who are willing to pay.
 - c. **Manitoba** – continues to offer test; has not been contacted by Myriad to stop testing.
 - d. **Ontario & Alberta** – continue to test despite demands by Myriad to stop testing.In January 2003, Ontario announced \$1.2 million in funding to provide non-Myriad approved BRCA1 and BRCA2 testing in that province.
7. To date, Myriad has taken no further action against Ontario or Alberta and as of early January 2003 has not demanded that Manitoba cease testing.
8. Myriad claims that attempts made by it, to date, to settle the matter amicably have failed.
9. This dispute is important in that it reveals the tension between patents and the provision of publicly funded health care in Canada; the handling of this dispute by the federal and provincial governments that continue to offer testing important for the precedent it sets.

See, Canadian Intellectual Property Office, Canadian Patents Database, online: CIPO
<<http://patents1.ic.gc.ca/intro-e.html>>.